



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Wisotzkey, Robert G.

Examiner:

Chen, Shin-Lin

Serial No.:

10/603,182

Group Art Unit:

1632

Filed:

June 24, 2003

Docket No.:

R2243/75658.485

Confirmation No.

1519

Title:

SLC19A2 Amino Acid Transporter Gene Disruptions, Compositions and

Methods Related Thereto

## RESPONSE TO RESTRICTION REQUIREMENT

MS AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's restriction of the claims mailed October 26, 2005, Applicant hereby provisionally elects, with traverse, Invention I (claims 1-13).

In the restriction, the Examiner asserts that claims 1-15 are drawn to two distinct subjects, grouped as Invention I (claims 1-13), drawn to a transgenic mouse comprising a disruption in an endogenous SLC19A2 gene, a method of producing the transgenic mouse, the transgenic mouse produced by said method, and a cell or tissue obtained from the transgenic mouse, and Invention II (claims 14 and 15), drawn to a targeting construct comprising a first and second polynucleotide sequence homologous to the endogenous SLC19A2 gene and a selectable marker sequence located between the first and second polynucleotide sequence, and a murine embryonic stem cell comprising said targeting construct. Applicant respectfully requests reconsideration and withdrawal of the requirement.

As stated in MPEP §803, the requirements for a proper claim restriction are as follows: "(a) the inventions must be independent or distinct as claimed; and (b) there must be a serious burden on the examiner if restriction is required."

A proper claim restriction must place a "serious burden" on the Examiner if the claims were examined without a restriction. In order to establish a serious burden, the Examiner must

"show by appropriate explanation one of the following: separate classification thereof, a separate status in the art, or a different field of search." This showing of a serious burden is required even if the claimed inventions have been shown to be distinct. See MPEP §808.02.

The instant Office Action generally asserts that restriction is warranted between the invention groups in that the claimed inventions are patentably distinct. The Examiner states that the inventions are related as product and process of use, and are patentably distinct because the products can be used in a materially different process. The Examiner has provided examples of how the products can be used in processes materially different than those related to producing the transgenic mouse, but the examples provided do not appear to be realistic. For example, the Examiner asserts that the cells of Invention II can be used to make recombinant protein. However, as the cells are embryonic stem cells and comprise a disrupted SLC19A2 gene, such cells would not be capable of producing functional protein. Further, it is unclear what target sequence the targeting construct would be used as a probe to identify, as the construct comprises a selectable marker sequence disrupting the endogenous gene. Applicant submits that the claimed inventions are closely related in that they have similar functions and uses, which relate to creating and using a SLC19A2 knockout mouse, and related structures, in that they comprise SLC19A2 gene disruptions.

More importantly, Applicant submits that the Examiner has not established that a serious burden would result from a search of the invention groups together, which is required even when the invention groups have been shown to be patentably distinct. Applicant does not believe that the Examiner has fulfilled the requirements for a proper claim restriction based on a serious burden standard. Applicant believes that a search of either invention group I or II would produce results that would encompass the subject matter of both invention groups. For example, the claims of provisionally elected invention I relate to a transgenic mouse comprising a disruption in the endogenous SLC19A2 gene. Any search or examination of the prior art conducted on this subject matter, e.g. SLC19A2 knockout mice, would produce results encompassing a targeting construct targeting the SLC19A2 gene and a murine embryonic stem cell disrupted by the targeting construct. As a result, separate searches of the prior art would not be required. Therefore, a serious burden would not be placed on the Examiner in order to conduct a search and examination of the claims of Inventions I and II together.

Although Applicant has provisionally elected Invention I for the purposes of advancing prosecution of the present application, Applicant contends for the foregoing reasons that the requirement for restriction is improper. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the requirement.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 502775.

Respectfully submitted,

John E. Burke, Reg. No. 35,836

Greenberg Traurig LLP 1200 17<sup>th</sup> Street, Suite 2400

Denver CO 80202

(303) 685-7411

(303) 572-6540 (fax)